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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,979	03/22/2001	Gary de Jong	24601-416	7635

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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/815,979	Applicant(s) DE JONG ET AL.	
	Examiner Daniel M. Sullivan	Art Unit 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *15-29 and 34-47*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3-14,30-32,59,61-64 and 144-147*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Daniel M Sullivan, Ph.D.
Examiner
Art Unit: 1636

Continuation of 3. NOTE: The claims have been amended such that the delivery agent applied to the cell must enhance permeability of the cell to the nucleic acid molecule compared to in its absence in the composition. As the delivery agent was applied to the cell was not previously so limited (see the Office Action mailed 10 March 2006, p. 4, 1), entry of the amendment would require a new consideration of the art and a new search to determine if the claims as amended are novel and non-obvious. Therefore, entry of the amendment would raise new issues that would require further consideration and search..

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 1, 3, 4, 6, 7, 9, 10-14 and 30-32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Marschall et al. (1999) Gene Ther. 6:1634-1637 as evidenced by Lipofectamine™ Reagent product description, available from Invitrogen™ life technologies or Transfectam™ Reagent product description, available from Promega.

The majority of Applicant's arguments contend that the culture medium used in the method of Marschall et al. cannot be construed as an agent an agent that enhances the permeability of a cell to a nucleic acid. However, even if this were the case, as the amendment has not been entered the delivery agent applied to the cells is not limited to enhancing the permeability of a cell for the reasons set forth in the 10 March Office Action, p. 4, 1. Therefore, Applicant's arguments are moot.

It is again pointed out that the limitation "delivery agent" is defined on page 13 of the specification as, "compositions, conditions or physical treatments to which cells and/or nucleic acids may be exposed in the process of transferring nucleic acids to cells in order to facilitate nucleic acid delivery into cells". In light of this definition, culture medium is construed as a "delivery agent" because the culture medium can reasonably be viewed as a composition that facilitates nucleic acid delivery into cells because it provides a medium through which the nucleic acid is contacted with the cell. The interpretation of the claim limitation is fully consistent with Applicant's own broad definition of "delivery agent" in the specification.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §102(b) as anticipated by the art.

Claims 1-14, 30-32, 59, 61-64 and 144-147 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hadlaczky et al. (2/2000) US Patent No. 6,025,155 (previously made of record) in view of Marschall et al. (supra) as evidenced by Lipofectamine™ Reagent product description (supra) or Transfectam™ Reagent product description (supra).

Applicant's arguments with regard to the instant obviousness rejection are again based on the assertion that the culture medium used in the methods disclosed in the art cannot be construed as a delivery agent. These arguments are not persuasive because, as discussed above, the interpretation of the claim is fully consistent with Applicant's own broad definition of "delivery agent" in the specification and, with regard to "increasing permeability", the claims do not require that a delivery agent that increases permeability be used. Therefore, Applicant's arguments with regard to enhancing permeability are not persuasive, at least, because the claims do not require that the cells be contacted with a delivery agent that enhances permeability.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §103(a) as obvious over the art..